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July 20, 2012

BY E-FILING AND FAX

The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 09-037-RBK-JS

Dear Judge Schneider:

Pursuant to the Court's July 13, 2012 oral order, we write on behalf of Plaintiff Shionogi Pharma, Inc. ("Shionogi") to address the issue of when Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") should be required to produce unexpired samples of its ANDA product. *See* July 13, 2012 Status Hearing Transcript ("Tr.") at 77:16-18.

A. Background

On May 23, 2012, Shionogi requested that Mylan produce a total of 150 representative tablet samples of each of its 500 mg and 1000 mg ANDA products, taken from at least 15 different manufacturing lots, because the samples Mylan previously produced in response to Shionogi's Request for Production No. 29 had expired. *See* D.I. 487, Ex. U. Shionogi made an identical request to Defendant Lupin. At the July 13th hearing, the Court stated that Defendants "ought to provide these samples" in the requested quantities. *See* Tr. at 27:16-25, 28:11-17.

Mylan's counsel has represented to the Court and to Shionogi—a representation upon which Shonogi relies—that Mylan has no unexpired product and is not currently manufacturing any of its ANDA product. *Id.* at 72:22-24. Shionogi requested that Mylan supplement its response to Request for Production No. 29 by producing product samples when manufacturing begins. Although Mylan agreed to produce the requested samples when and if it begins commercial sale

of its product, Mylan takes the position that it need not provide those samples to Shionogi at any earlier date. Tr. at 77:8-12.

Shionogi respectfully requests that, consistent with the requirements of the Federal Rules of Civil Procedure and the Hatch-Waxman Act, the Court order Mylan to produce the requested samples when Mylan begins manufacturing them.

B. Mylan has a Duty to Supplement its Production

The Federal Rules of Civil Procedure require that a party supplement its response to a request for production "in a timely manner" or "as ordered by the court." *See* Fed. R. Civ. P. 26(e)(1)(A) and 26(e)(1)(B). The duty to supplement is a continuing duty, and a "party may not free itself of the burden to fully comply by placing a heretofore unrecognized duty of repeated requests for information on its adversary." *AVX Corp. v. Cabot Corp.*, 251 F.R.D. 70, 76 (D. Mass 2008).

Mylan does not dispute that it will produce the requested samples of its unexpired product;[1] nor does it dispute that the Court has ordered such production. *See* Tr. at 27:16-25, 28:11-17. The only dispute before the Court is the timing of that production, if Mylan's unexpired product becomes available.

C. Mylan is Required to Supplement Its Production in a Timely Manner

Under the Federal Rules of Civil Procedure, Mylan must supplement its production "in a timely manner," and the Court can order Mylan to produce the requested samples when Mylan begins to manufacture its product. *See* Fed. R. Civ. P. 26(e)(1)(A)-(B). So long as Mylan's product samples have been manufactured and are available to produce to Shionogi, Mylan should not be permitted to wait until after it launches its product to make that production.

During the hearing, counsel for Mylan stated that Mylan merely had a duty to "seasonably supplement" and argued that it was therefore not obligated to produce samples until after launch. *See* Tr. at 74:18-19. First, "seasonably supplement" is no longer the standard; the Federal Rules were modified in 2007 to require that supplementation occur "in a timely manner."[2] That language on its face does not permit a party to deliberately delay its production. Even under the prior rule, however, Mylan's proposed delay would not be permitted. The Advisory Committee Notes to Rule 26(e) then provided that supplementation should occur "with ***special promptness*** as the trial date approaches." *See* Fed. R. Civ. P. 26(e), Advisory Committee Notes, 1993 Amendments (emphasis added). The same should hold true for material that is highly relevant to preliminary injunction proceedings. Mylan should not be allowed to purposefully wait until after it launches to produce its product samples, thereby thwarting Shionogi's ability to test those products in a timely manner prior to preliminary injunction proceedings. *See Zoltek Corp. v.*

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[1] For each dosage, 500mg and 1000mg tablet, Shionogi has requested 150 tablets total taken from 15 different lots (*i.e.* 10 tablets from each lot).

[2] Fed. R. Civ. P. 26(e), Advisory Committee Notes, 2007 Amendment.

U.S., 71 Fed. Cl. 160, 171 (Fed. Cl. 2006) ("delaying production to gain a strategic advantage would be improper and borders on bad faith").

Moreover, the Hatch-Waxman Act requires that in cases brought under that statute, "each of the parties shall reasonably cooperate in expediting the action." 21 U.S.C. § 355 (j)(5)(B). There is no reason why Mylan cannot "reasonably cooperate" in expediting this action, or a preliminary injunction proceeding, by promptly providing the requested samples as it manufactures them.

The same result applies under the current articulation of Rule 26(e)(1)(A), which requires supplementation "in a timely manner." *See Robbins & Myers, Inc. v. J.M. Huber Corp.*, 274 F.R.D. 63, 78 (W.D.N.Y. 2011) (holding that the duty to provide supplemental disclosure of facts and documents "in a timely manner" as required by Rule 26(e)(1)(A) "accrued immediately upon their creation and was not contingent upon Defendants serving Plaintiff with a request for supplementation"); *Adams v. Teck Cominco Alaska, Inc.*, 231 F.R.D. 578, 580 (D. Ala. 2005) (holding that Rule 26(e) places the burden on the producing party to supplement its disclosures and update "information as it becomes available").

Accordingly, the Court should order Mylan to produce the requested sample products as soon as they become available, *i.e.*, upon their manufacture.

D. The Issue of Pre-Launch Notice is Irrelevant with Respect to Mylan's Production of Samples

Mylan argues that because it is not required to provide Shionogi with notice of its launch, it should be able to wait until after launch to produce product samples to avoid giving Shionogi any advance notice that it is manufacturing product in preparation for a launch. Mylan's position is, as noted above, inconsistent with both the requirements of Rule 26(e)(1) and the Hatch-Waxman Act.

First, Mylan has the ability to produce its samples on an attorneys-eyes-only basis. As the Court has already ruled, the Protective Order provides sufficient protection to protect against any competitive harm.

Next, the fact that Mylan's production of samples could also provide pre-launch notice to Shionogi does not obviate Mylan's discovery obligations under the Federal Rules. Although a potential byproduct of the requested production could be knowledge that Mylan is preparing for a commercial launch, that fact is irrelevant to whether Mylan is required to meet its discovery obligations. In addition, the knowledge that product is being manufactured does not provide Shionogi with any information about the actual timing of a launch. At most, Shionogi could only infer that such a launch is possible, at some future date.

In any event, that information would allow the Court to manage its docket efficiently, by allowing Shionogi to conduct timely testing of product in advance of a preliminary injunction hearing. At the July 13 hearing, Mylan argued that the Federal Circuit's recent decision vacating the preliminary injunction against Lupin makes the issue of a preliminary injunction prior to a launch a moot point. The Federal Circuit's decision, however, involved only one of the two

patents-in-suit, the '866 patent.[3] There is a second patent—the '859 patent—asserted against Mylan, and the facts and circumstances upon which the Federal Circuit based its decision involving the '866 patent do not apply to the '859 patent.

Even if Mylan were correct that the possibility of a preliminary injunction is now moot, that argument supports Shionogi, not Mylan. Assuming Mylan were correct that the preliminary injunction issue is moot, then its argument that the requested production is an "end-around" by Shionogi to gain advance notice of launch for a preliminary injunction is also moot. On the other hand, if Shionogi is correct and the possibility of a preliminary injunction is not a "dead letter," then the fact that Shionogi's requested production might also provide some notice of the possibility of a launch is mere happenstance, and certainly not a dispositive factor for why Mylan should not be required to produce samples in a timely manner as required by the Federal Rules.

For the foregoing reasons, Shionogi respectfully requests that the Court order Mylan to produce the requested product samples as soon as they become available, if and when it begins manufacturing.

Respectfully submitted,

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)

cc: All Counsel of Record

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[3] Shionogi continues to believe that neither Lupin and/or Mylan will ultimately meet their burden of proving the '866 patent invalid by clear and convincing evidence.